#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE.

Appellant(s): Boza et al. Appl. No.: 09/646,748

Conf. No.: 7778

Filed: December 11, 2000

Title: METHOD FOR PROVIDING GLUTAMINE

Art Unit: 1654 Examiner: A. Mohamed

Docket No.: 112701-036

Mail Stop Appeal Brief - Patents Commissioner for Patents

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#### APPELLANTS' REPLY BRIEF

Sir:

### I. INTRODUCTION

Appellants submit Appellants' Reply Brief in response to the Examiner's Answer dated September 18, 2007 pursuant to 37 C.F.R. § 41.41(a). Appellants respectfully submit the Examiner's Answer has failed to remedy the deficiencies with respect to the Final Office Action dated October 16, 2006 as noted in Appellants' Appeal Brief filed on July 3, 2007 for at least the reasons set forth below. Accordingly, Appellants respectfully request that the anticipation and obviousness rejections of pending Claims 1-16 be reversed.

## II. <u>OPTIMUM NUTRITION</u> AS EVIDENCED BY COSTELLO'S IS NOT PROPER PRIOR ART

Appellants respectfully request that the Board reverse the section 102 rejection because the Examiner has still failed to demonstrate that the earlier version of Optimum Nutrition (e.g., the product featured in the publication by Costello's is identical in formulation to the Optimum Nutrition being relied upon in the final Office Action dated October 16, 2006. For example, the whey protein product from Optimum Nutrition being relied upon in the final Office Action states that the formulation is "better than ever," which suggests that the formulation has been modified from an earlier version. Furthermore, the website for Optimum Nutrition currently discloses that the most recent formulation of the whey protein product is the third generation of Optimum Nutrition whey protein products.

The Examiner asserts that because the Costello's catalogue lists 100% whey protein product (codes 02 288 and 02 289) and Optimum Nutrition discloses a product with the same name, that the products must automatically be the same. In response, Appellants' respectfully submit that just because a product's trade name does not change does not mean that the product's formulation does not change. As Appellants' have previously discussed, why would Optimum Nutrition have the need to improve its formulation to provide second or third generations. If the Optimum Nutrition product remained the same formulation, the currently sold product would likely state that it comprises the original formulation or make no reference to improvements. Because the formulation has changed, it remains possible that Costello's nutritional product referred to by the Examiner does not disclose or suggest the same protein formulation as that disclosed by Optimum Nutrition. As a result, Costello's nutritional product may have also provided additional protein sources besides whey protein that amount to more than 20% of the total protein source.

In sum, Appellants respectfully submit that Examiner has not definitively shown that the Optimum Nutrition product formulation cited against the pending application is the same product formulation sold by Costello's. Accordingly, Appellants respectfully submit that the product disclosed by Optimum Nutrition was not on sale or publicly disclosed before the priority date of the present application (i.e. March 31, 1998) and therefore does not anticipate the present claims.

## III. OPTIMUM NUTRITION AS EVIDENCED BY COSTELLO'S FAILS TO DISCLOSE THE CLAIMED INVENTION

Appellants respectfully request that the Board reverse the section 102 rejection because the Examiner has still failed to demonstrate that the cited references disclose every element of independent Claim 1. For example, Optimum Nutrition as evidenced by Costello's fails to disclose or suggest a method comprising administering a nutritional compound to a stressed mammal to increase its plasma glutamine concentration as required, in part, by Claim 1.

The Examiner asserts that the term "stressed animal" is a non-limiting condition. Appellants respectfully disagree. For example, Claim 1 requires the method step comprising administering a nutritional compound to a stressed mammal to increase its plasma glutamine concentration. As a result, the administering to a stressed mammal is included in the body of a claim and is directed to a specific condition of a mammal that receives the nutritional composition.

The Examiner also asserts that administering the whey protein to a stressed mammal would automatically increase its plasma glutamine concentration. Nevertheless, Appellants respectfully submit that the Examiner is misunderstanding the initial requirement of Claim 1, which is to administer the nutritional compound to a stressed mammal. *Optimum Nutrition* as evidenced by *Costello's* fails to disclose or suggest this element. In fact, *Optimum Nutrition* as evidenced by *Costello's* fails to mention anything about administering its composition to a stressed mammal. Nowhere does *Optimum Nutrition* as evidenced by *Costello's* even discuss a stressed mammal. Accordingly, Appellants respectfully submit that the cited references fail anticipate the claimed subject matter and the anticipation rejection should be reversed.

# IV. THE EXAMINER HAS STILL FAILED TO ESTABLISHED A PRIMA FACIE CASE OF OBVIOUSNESS

Appellants respectfully request that the Board reverse the section 103 rejection because the Examiner has still failed to demonstrate why the skilled artisan would have combined the cited references to arrive at the present claims. This is demonstrated by a review of the references <u>as a whole</u> and those portions teaching away each other and/or the claimed invention. Instead, it is respectfully submitted that the Examiner has <u>improperly attempted to combine references that have different intended purposes</u>. Appellants respectfully submit that the Examiner has failed to consider the intended purposes of the references.

The whole premise of Ballevre is that carob protein is rich in glutamine and that <u>its</u> nutritional composition for improving plasma glutamine should include carob protein. Ballevre further teaches that its mixture of carob and whey proteins uses whey protein as the minor rather than the major component. See, Ballevre, column 4, lines 27-35; Example 2. For example, Ballevre discloses that <u>carob protein</u> comprises about 40% to about 100% by weight of the protein source of its nutritional composition, which results in the protein source in Ballevre containing a minimum of "about 40%" of the protein source of carob. Because Ballevre teaches that it is essential to retain carob protein, it teaches away from the present claims and a combination with Optimum Nutrition that is said to be directed to a product comprising 100% whey proteins to assist in body building.

The Examiner asserts that, given the teachings of Optimum Nutrition regarding a nutritional composition comprising of 100% whey protein for dietary supplement, the skilled artisan would have been motivated to adapt the composition of Optimum Nutrition with the teachings of Ballevre relating to administering a nutritional composition to stressed patients. Appellants respectfully disagree. For example, the specific formulation for each product as taught by the cited references is important and specific to the intended purpose of that particular product. Ballevre product comprising a majority of carob protein is specifically designed for stressed patients. Optimum Nutrition's dietary product comprises a completely different formulation having no carob protein and is not designed for stressed mammals. In fact, Optimum Nutrition's make no mention of stressed mammals. Because of the differences in intended purposes for each product, one skilled in the art would not be motivated to modify or combine Optimum Nutrition and Ballevre to arrive at the present claims, and the combination of the cited references is improper.

Appellants also respectfully request that the Board reverse the section 103 rejection because the Examiner has still failed to demonstrate that the cited references disclose or suggest every element of the present claims. For example, Ballevre and Optimum Nutrition as evidenced by Costello's fail to disclose or suggest a method comprising the step of administering a

nutritional compound to any stressed mammal to increase its plasma glutamine concentration as required, in part, by Claim 1. Ballevre and Optimum Nutrition as evidenced by Costello's also fail to disclose or suggest a method comprising the step of administering to a mammal suffering from injured, diseased or under-developed intestines a nutritional compound to increase its plasma glutamine concentration as required, in part, by Claim 3.

In sum, Appellants have shown that the cited references teach away from the proposed combination and/or the present claims because they each have different intended purposes. As a result, the skilled artisan has no reason to combine Ballevre and Optimum Nutrition as evidenced by Costello's to arrive at the present claims, and the combination of the cited references is improper. Moreover, the cited references, alone or in combination, do not teach, suggest, or even disclose all of the elements of independent Claims 1 and 3 and the claims that depend from Claims 1 and 3. Accordingly, Appellants respectfully submit that the cited references fail to render the claimed subject matter obvious and the obviousness rejection should be reversed.

### V. CONCLUSION

For the foregoing reasons, Appellants respectfully submit that the Examiner's Answer does not remedy the deficiencies noted in Appellants' Appeal Brief with respect to the Final Office Action. Therefore, Appellants respectfully request that the Board of Appeals reverse the anticipation and obviousness rejections with respect to Claims 1-16.

No fee is due in connection with this Reply Brief. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-36 on the account statement.

Respectfully submitted,

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BY

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Dated: November 16, 2007